CLAIMS

1. An isolated recombinant human arginase I having substantially the same amino acid sequence as set forth in Fig. 2C and having a purity of 80-100%.

2. The recombinant human arginase I according to claim 1 further having six additional histidines attached to the amino terminal end thereof.

3. The recombinant human arginase I according to claim 1 or 2 having a specific activity of at least 250 I.U./mg.

4. The recombinant human arginase I according to claim 3 having a specific activity of 500 to 600 I.U./mg.

5. The recombinant human arginase I according to claim 4 comprising modification resulting in an *in vitro* plasma half-life of at least approximately 3 days.

6. An isolated recombinant human arginase I according to claim 1 or 2 having a purity of at least 90%.

7. The recombinant human arginase I according to claim 5, wherein said modification is pegylation.

8. The recombinant human arginase I according to claim 7, wherein said pegylation results from covalently attaching at least one polyethylene glycol (PEG) moiety to said arginase using a coupling agent.

9. The recombinant human arginase I according to claim 8, wherein said coupling agent is selected from the group consisting of 2,4,6-trichloro-s-triazine (cyanuric chloride, CC) and succinimide propionic acid (SPA).

10. A method of producing recombinant protein comprising:

(a) cloning a gene encoding said protein;

(b) constructing a recombinant *Bacillus substilis* strain for expression of said protein;

(c) fermenting said recombinant *Bacillus subtilis* cells using fed-batch fermentation;

(d) heat-shocking said recombinant *Bacillus subtilis* cells to stimulate expression of said recombinant protein; and

(e) purifying said recombinant protein from the product of said fermentation.

11. The method according to claim 10 wherein said *Bacillus subtilis* is a prophage.

12. The method according to claim 10 or 11 wherein said protein is human arginase I.

13. The method according to claim 12 wherein said human arginase I has six histidines linked to the amino-terminus thereof, and said purifying step comprises affinity chromatography in a chelating column.

14. The method according to claim 12 wherein said fermenting step is performed using a feeding medium consisting essentially of 180-320 g/L glucose, 2-4 g/L $MgSO_4 \bullet 7H_2O$, 45-80 g/L tryptone, 7-12 g/L K_2HPO_4 and 3-6 g/L KH_2PO_4.

15. A pharmaceutical composition comprising an isolated and substantially purified arginase.

16. The pharmaceutical composition according to claim 15 wherein said recombinant human arginase is human arginase I.

17. The pharmaceutical composition according to claim 15 wherein said recombinant human arginase is human arginase I containing six additional histidines attached to the amino terminal end thereof.

18. The pharmaceutical composition according to claim 15, wherein said composition is further formulated in a pharmaceutically acceptable carrier.

19. The pharmaceutical composition according to claim 15, wherein said formulation of said pharmaceutical composition is in a form suitable for oral use, for a sterile injectable solution or a sterile injectable suspension.

20. The pharmaceutical composition according to claim 16, wherein said recombinant human arginase I has a specific enzyme activity of at least 250 I.U./mg.

21. The pharmaceutical composition according to claim 20, wherein said recombinant human arginase I has a specific enzyme activity of 500 to 600 I.U./mg.

21. The pharmaceutical composition according to claim 16, wherein said recombinant human arginase I has a half-life in said patient plasma of at least 3 days.

22. The pharmaceutical composition according to claim 21, wherein said recombinant human arginase I has a half-life in said patient plasma of approximately at least 1 day.

23. The use of the human arginase I of claim 1 for the preparation of a medicament.

24. The use according to claim 23 wherein said medicament is used for the treatment of human malignancies.

25. The use according to claim 24 wherein said human malignancies are liver tumour, breast cancer, colon or rectal cancer.

26. A method of treatment of human maligancies comprising administering recombinant human arginase into a patient.

27. A method of treatment of human maligancies in a patient comprising administering a pharmaceutical composition that reduces the physiological arginine level in said patient to below 10 μM for at least 3 days.